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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,480	06/14/2002	Alexandr Vilenovich Asafov	RUPA 19.411	3960

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EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,480	ASAFOV ET AL.	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 2-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isotonic plasma substitute composition comprising no more than 0.5% by weight of a physiologically acceptable salt of DNA obtained from sturgeon milt or salmon milt having an average molecular weight of 1.5 x 10^3 D to 550 x 10^3 D, and having no more than 1.5% by weight protein, no more than 2% by weight polysaccharides and no more than 6% by weight RNA, does not reasonably provide enablement for a plasma substitute containing a physiologically acceptable salt of a DNA derivative prepared from animal raw material. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' showing is limited to specific sources and contents of the plasma substitute. Applicant provides no guidance as to other appropriate sources or any discussion of the nature of the "derivation" required to prepare the composition. Since the specification is a translation of a foreign document, the meaning of the term "derivative" is not clear. Per the citation of the prior art and per the discussion in the Background of the Invention found at pages 1, 2 and 3 of the specification, traditional and conventional blood substitutes are formed either from inactive molecules, such as dextran, that provide proper isotonicity to be used as a plasma expander or components normally found in plasma that have oxygen-carrying capacity such as hemoglobin.

There is no disclosure of the use of molecules such as DNA, which are not normally found circulating in the blood or the tissues of a human. In fact, it is the presence of antibodies to DNA in the blood that are indicative of certain disease states associated with autoimmune conditions such as autoimmune thyroiditis. Given the fact that DNA is not usually found in the blood, there is an unpredictability in the art that would suggest that such molecules are not equivalent to the inactive tonicity agents such as dextran, polyglucin or polyvinylpyrolidone, and therefore, one of ordinary skill in the art would be unable to select any other DNA source or determine what type of "derivative" would be appropriate without engaging in undue experimentation and would not have a reasonable expectation of success.

2. Claims 2-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" renders the claims vague and indefinite as it fails to distinctly define the nature of the "derivation" or change required to the claimed composition. In claim 7 and 12, the term "hyperchromic effect (28-47%)" renders the claims vague and indefinite since it is unclear as to the meaning of the percentage range after the term. "Hyperchromic" is a term descriptive of erythropoietic cells when they stain more darkly than normal due to increased thickness of the cells and also describes a type of anemia characterized by a reduction of red blood cells where existing cells are more deeply colored than normal. It is not clear 1) how the term is being used in the claim and 2) how it refers to the plasma substitute. In claim 8, Cyrillic

letters appear after the term "derivative" and render the claim vague and indefinite as the meaning of these letters is not apparent. In claims 8 and 13, the term "$(5x10^3–5)$g per 1 L" is vague and indefinite; the type of scientific notation is not conventional and therefore the dose claimed is unknown.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,914,391 to Gerber et al.

U.S. Patent 5,914,391 to Gerber et al. teaches an isotonic plasma substitute that stimulates hematopoiesis and inhibits aggregation, which can increase immunogenicity of the substitute. These characteristics fall well within broadest reasonable interpretation of the terms "hemocorrecting effects", "immunomodulating effects" and "capable to activate the hematopoietic system". Therefore, the referenced substitute is deemed to have hemocorrecting and immunomodulating effects and is capable to activate the hematopoietic system and anticipates the cited claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jean C. Witz
Primary Examiner
Art Unit 1651